

## Message Text

UNCLASSIFIED

PAGE 01 STATE 104635

70

ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 /024 R

66611

DRAFTED BY: DHEW/FDA/LRSHELTON

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EUR/WE:KHSHIRLEY (INFO)

----- 030075

R 052136Z MAY 75

FM SECSTATE WASHDC

TO AMEMBASSY THE HAGUE

UNCLAS STATE 104635

E.O. 11652: NA

TAGS: OCON, OGEN, TBIO, NL

SUBJECT: TECHNICAL CONSULTATIVE VISIT: VITATRON MEDICAL,  
DIEREN, THE NETHERLANDS

1. SUBJECT FIRM HAS HAD A RECALL BY FDA OF A PACEMAKER  
DISTRIBUTED IN U.S. REASON: DESIGN PROBLEMS INVOLVING  
BATTERY ELECTROLYTE CONTAMINATION OF PACEMAKER ELECTRICAL  
CIRCUITRY.

2. FDA HAS NEED TO DETERMINE AT FIRST-HAND WHAT FIRM HAS  
DONE TO MINIMIZE OR ELIMINATE POSSIBILITY OF FAILURE OF PACE-  
MAKER WHICH COULD RESULT IN PREMATURE EXPLANATION.

3. TO OBTAIN THIS INFORMATION, STUDY QUALITY  
CONTROL PROCEDURES, ETC, FDA WILL HAVE W.F. HOTTEN, ENGINEER,  
AND D.R. BEARDSLEY, INVESTIGATOR, VISIT THE FIRM MAY 12-14,  
1975. FIRM IS AGREEABLE TO VISIT. GON CONCURRENCE BEING  
OBTAINED BY EMBASSY IN WASHINGTON.

4. WHILE EMBASSY ASSISTANCE IS NOT REQUIRED, TRAVELERS WILL  
BE PLEASED TO DISCUSS, IF EMBASSY SO DESIRES. CAN BE CONTACTED  
THROUGH VITATRON. KISSINGER

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PAGE 02 STATE 104635

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** n/a  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 05 MAY 1975  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1975STATE104635  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** DHEW/FDA/LRSHELTON  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D750157-0834  
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**Handling Restrictions:** n/a  
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**Line Count:** 60  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 2  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
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**Review Authority:** ShawDG  
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**Review Date:** 14 JUL 2003  
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**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** TECHNICAL CONSULTATIVE VISIT: VITATRON MEDICAL, DIEREN, THE NETHERLANDS  
**TAGS:** OCON, OGEN, OSCi, OTRA, NL  
**To:** THE HAGUE  
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